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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,605	12/23/2003	Wee Song, Steve Loy	BCONP2003-13	1604
31366	7590	11/04/2009	EXAMINER	
HORIZON IP PTE LTD 7500A Beach Road #04-306/308 The Plaza SINGAPORE 199591, SINGAPORE			JARRETT, RYAN A	
			ART UNIT	PAPER NUMBER
			2121	
			NOTIFICATION DATE	DELIVERY MODE
			11/04/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/707,605	<b>Applicant(s)</b> LOY ET AL.	
	<b>Examiner</b> RYAN A. JARRETT	<b>Art Unit</b> 2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,12-15 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,12-15 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/07/09 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12-15, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al. US 6,456,955.

1. A method of automating validation comprising:  
defining requirements (e.g., col. 1 line 9 – col. 2 line 14);  
selecting automated devices for manufacturing (e.g., Fig. 1 #10, 12, 14, 16, col. 3 lines 34-40);  
integrating automated devices in a production line (e.g., Fig. 1 #10, 12, 14, 16, col. 3 lines 34-40), wherein integrating the automated devices comprises interconnecting the automated

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devices to a hub-box (e.g., Fig. 1 #18, Fig. 2B #114, Fig. 3) via communication links, the hub-box operationally controls (e.g., col. 3 line 40 – col. 4 line 29: “automated method”, “the application creates a matrix 104 with a specific sample and method queue within the Millennium application...The matrix determines the chemistries and mathematical algorithms employed within a specific chromatography column”, “the additional tests needed for qualification are then performed automatically without the need for trained operator 100 intervention”, Table 4: “Control Values”) and facilitates communication between automated devices (e.g., Fig. 2B #114, *The automated tool collects data from the devices and controls the devices, so clearly there is communication between the automated tool/hub-box and the devices*) and validation of the manufacturing process, wherein the validation includes generating an organized set of documents, defining aspects of the process, in conformance with regulatory standards (e.g., Fig. 2B #116-118, col. 2 lines 15-64);

collecting processing data from the automated devices by the hub-box for analysis (e.g., Fig. 2B #114);

analyzing processing data to determine whether the requirements are satisfied (e.g., Fig. 2B #19: “ACCEPTABLE?”); and

validating the manufacturing process if the requirements are satisfied (e.g., Fig. 2B: “QUALIFICATION COMPLETED & PASSES”).

12. The method of claim 1 further comprises providing a generic interface unit for facilitating communication between the hub-box and automated modules (e.g., col. 5 line 54 – col. 6 line 21).

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13. The method of claim 12 wherein providing the generic interface unit comprises providing a generic interface for each automated module (e.g., col. 5 line 54 – col. 6 line 21).

14. The method of claim 13 wherein the generic interface includes communication links for each automated device of the automated module (e.g., col. 5 line 54 – col. 6 line 21).

15. The method of claim 12 wherein the generic interface includes communication links for each automated device of the automated module (e.g., col. 5 line 54 – col. 6 line 21).

21. The method of claim 1 wherein the requirements are user requirements or functional requirements (e.g., col. 1 line 9 – col. 2 line 14).

22. The method of claim 21 wherein the user requirements are facility operating conditions, desired output, quality, process or product specifications (e.g., col. 1 line 9 – col. 2 line 14).

23. The method of claim 21 wherein the functional requirements are power consumption, loading, speed or capacity, environmental operating conditions, system or equipment functionalities, process results or quality parameters (e.g., col. 1 line 9 – col. 2 line 14).

24. The method of claim 1 wherein the documents contain information relating to change history, operating conditions, events, alarm messages, control parameters, process parameters, measurement data or analysis results (e.g., col. 4 lines 49-64).

25. The method of claim 1 wherein the documents are audit trail reports, electronic records or electronic signatures (e.g., col. 5 lines 21-36).

***Response to Arguments***

Applicant's arguments filed 10/07/09 have been fully considered but they are not persuasive. Applicants say they are unable find communication links between the automated devices and the hub-box. However, the automated tool of Andrews collects data from the devices and controls the devices, so there must be communication links between the automated tool and the devices.

Applicant also argues that there is no disclosure of a hub-box operationally controlling the automated devices. However, Andrews discloses an “automated method”, “the application creates a matrix 104 with a specific sample and method queue within the Millennium application...The matrix determines the chemistries and mathematical algorithms employed within a specific chromatography column”, “the additional tests needed for qualification are then performed automatically without the need for trained operator 100 intervention”, Table 4: “Control Values” (e.g., col. 3 line 40 – col. 4 line 29). This automated methodology is performed by a centralized automated tool (e.g., Fig. 1 #18, Fig. 2B #114, Fig. 3), which corresponds to the claimed hub-box.

***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan A. Jarrett whose telephone number is (571) 272-3742. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Decady can be reached on (571) 272-3742. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan A. Jarrett/  
Primary Examiner, Art Unit 2121

10/29/09